

## **REMARKS**

### **I. Claims in the Case**

Claim 7 has been amended to introduce the subject matter of claims 1-4, and new claims 22-29 have been added the break out the individual promoters of claim 7 (claims 22-25) and claim 13 through claim 10 (claims 26-29). Accordingly, claims 7-11, 13, 16 and 19-29 are pending.

### **II. Claim Objections**

Claim 7 was objected to as depending from cancelled base claims. Claim 7 has been amended to incorporate the language from claims 1-4.

Claim 10 have been objected to as broadly encompassing non-elected inventions and the Examiner requests that claim 10 be amended to reflect the elected invention.

In response, Applicants are unaware of any rule supporting the Examiner's objection or request. If the Examiner could recite the specific rule being relied upon or MPEP section, Applicants would be pleased to take the Examiner's request under consideration.

### **III. Written Description Rejections**

The Action next rejects newly added claims 19-21 as containing subject matter allegedly not adequately disclosed in the application as filed. The Examiner appears to take the position that the reference to "ornamental fish in the market" in the patent specification is limited to GFP fish.

In response, this position is unsound on its face. The title of the section relied upon by the Applicants for support of these claims is "Potential Applications of *Fluorescent Transgenic Fish*" (emphasis supplied), and is not limited to GFP fish in the slightest. Furthermore, the first sentence of that section states: "*The fluorescent transgenic fish* have use as ornamental fish in

the market” (emphasis supplied) -- again, no limitation to GFP fish is made. Similarly, while that particular paragraph continues by making reference to green GFP fish, the very next paragraph expands this concept to include multiple colors of fish. Thus, the Examiner’s position is simply unsupported by the record.

Regarding the remaining language of claims 19-20 (*i.e.*, the language beyond the reference to ornamental) the Examiner is referred to original claims 8-9. Regarding the language of claim 21, which references “fluoresces upon exposure to sunlight,” the Examiner is referred to original claim 11.

#### **IV. Rejections Under 35 U.S.C. 112, Second Paragraph**

The Action next rejects all of the claims as indefinite, for reasons addressed below.

Regarding claim 7, this claim has been amended as suggested.

Regarding claim 8, this claim includes within its scope only fertile fish and thus does limit the subject matter of claim 7, which can be construed to cover fish that have a promoter in germ and/or somatic cells but for whatever reason might be infertile.

Regarding claim 9, it is noted that use of the word “progeny” does not require that *all* progeny are transgenic, just that some are.

Regarding claims 11 and 12, the elements of these claims are met so long as they appear to fluoresce in sunlight.

Regarding claim 16, this claim has been amended to incorporate the stringency conditions provided in the specification in the first full paragraph on page 13.

Regarding “ornamental fish” found in claims 19-21, Applicants submit that such term is exceedingly well known to those of skill in the art. For example, we have enclosed page 2B of the FDA Fish Classification Guide, one of the regulatory agencies that approves the commercial

distribution of transgenic ornamental fish, which provides a specific definition: “‘Ornamental and aquarium’ fish are defined as : fish that are produced and maintained solely for exhibit purposes in home or public aquaria, or in ornamental garden ponds.” Furthermore, specific examples of such ornamental fish are set forth in the specification at the bottom of page 22.

#### V. Rejection of Claims as Anticipated

Lastly, the Action rejects all of the claims as being anticipated by Moss *et al.* and Amsterdam *et al.*

Turning first to the Moss *et al.* reference, it is noted that nowhere does this reference disclose transgenic fish *per se*, it only appears to disclose transiently transgenic zebrafish embryos as opposed to transgenic fish, employing the rat MLC promoter. The Amsterdam *et al.* reference does describe stable transgenic lines in contrast to Moss *et al.*, but, again, the promoter employed by Amsterdam *et al.* is apparently the *Xenopus* efl $\alpha$  promoter (this is a frog promoter) not a fish promoter (see Figure 1 description, top of page 125). It is our position that the Examiner has failed to make a *prima facie* case of anticipation of any of the currently pending claims with respect to the Moss *et al.* reference:

**Claims 7-9 and 11:** The Moss *et al.* reference employs the *rat* MLC promoter in the zebrafish embryo studies using the construct identified as MLC-GFP. We know that this is the rat MLC promoter from the description of its construction in Figure 1, page 90. Thus, Moss *et al.* cannot anticipate any of the transgenic fish of claims 7-9, as these claims are concerned with various fish promoters, not rat promoters. Similarly, since the Amsterdam *et al.* reference apparently concerns the use of a *Xenopus* efl $\alpha$  promoter it cannot anticipate the transgenic fish of claims 7-9 or 11.

**Claim 10:** Similarly, Moss *et al.* has not been shown to anticipate claim 10 in that this reference is clearly concerned with only transiently transgenic zebrafish, as evidenced by the fact that it is noted in col. 2, page 96, that the fish were “mosaic” and in the last paragraph of that column it is stated that the article describes the use of GFP as a vital dye in “transient transgenic zebrafish” muscle..

With respect to the Amsterdam *et al.* reference, the Examiner has failed to show how that reference teaches any one of the subcategories of claim 10, i.e., the promoters specified under groups (1) – (4) of claim 10. For example, from a reading of the section entitled “Expression of GFP in Transgenic Lines” beginning on page 125 and extending through page 127, particularly Figure 2, it does not appear as though any of the described lines exhibit any one of the four characteristics set forth in groups (1) – (4) of claim 10, and the Examiner has not explained on the record just how he believes this reference anticipates claim 10.

**Claim 13:** Claim 13, which depends from claim 10, has not been shown by the Examiner to be anticipated for the combined reasons set forth above with respect to claim 10 and claims 7-9 and 11:

**Claim 16:** Claim 16 has not been shown to be anticipated in that this claim is directed to transgenic fish incorporating a promoter that hybridizes under stringent conditions to the zebrafish promoters of SEQ ID NOS: 7, 8, 9 or 22. The Examiner has provided no reasoning as to whether it would be expected that Moss’s rat MLC promoter would hybridize under stringent conditions to the specified zebrafish promoters. The same is true for the *Xenopus* promoter of Amsterdam *et al.* reference.

**Claim 19:** The Examiner has not pointed out where in either reference there is a description or teaching of using the fish as ornamental fish in the ornamental fish market.

**Claims 20 and 21:** Claims 20 and 21 are novel for the same reasons as claim 10, from which they depend. Furthermore, the Examiner has failed to explain how either of the references teach the subject matter set forth in these claims.


**Claims 22-25:** These claims depend from claim 7 and are novel for at least the same reason as claim 7, discussed above.

### **CONCLUSION**

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3055 is respectfully requested.

Respectfully submitted,

*FOR*  *GINA SHISHMA REG. NO. 45,104*  
David L. Parker  
Reg. No. 32,165  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201  
(512) 536-4598 (facsimile)

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